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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/381,561 09/17/99 JACKSON

J 2426-1-001

EXAMINER

HM12/1004

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PHAM, M

ART UNIT

PAPER NUMBER

1641

*10*

DATE MAILED:

10/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/381,561

Applicant(s)

JACKSON, JAMES RICHARD

Examiner

Minh-Quan K. Pham

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☒ The proposed drawing correction filed on 08 June 2000 is: a) ☒ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
  2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
  3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5&6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## **DETAILED ACTION**

### ***Claim Status***

Claims 1-19 are canceled in Paper No. 8, filed June 13, 2000. New claims 20-39 are presented in Paper No. 8.

Previous claim objections and rejections are moot, because claims 1-19 are canceled.

### ***Specification***

The abstract presented in Paper No. 8 is acceptable. The objection to the specification is withdrawn.

### ***Drawings***

The drawing corrections presented in Paper No. 8 are acceptable. The objection to the drawing is withdrawn.

### ***Information Disclosure Statement***

JP-5-135515A is not considered because a translation is not available.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 29, 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "small and light" in claim 21 is a relative term which renders the claim indefinite. The phrase "small and light" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear from the claim and the specification what is considered "small and light". The claim and the specification attempt to define "small and light" as the ability to facilitate handling and transport; however, this is not descriptive because almost anything can be handled and transported. For example, the space shuttle is "small and light" according to the definition because it can be handled and transported.

Claim 29 is indefinite because it is not clear from the specification what the "reagents for diluting said sample fluid" are.

Claim 34 recites the limitation "the assay reagents" in claim 34. There is insufficient antecedent basis for this limitation in the claim. It is not clear that the primary conduit has any assay reagents.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 20-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Chow (US 5,955,028).

Chow discloses a base unit to interface an assay substrate with a recording device, such as a computer, to control, record, and/or analyze the data from the microfluidic device (see column 5, line 25 to column 6, line 50). The assay substrate comprises a plurality of sample and reagent wells connected with microchannels (see column 11, line 48 to column 12, line 6; and Figure 1). Chow discloses an assay substrate (assay part) that is removable from a computer (recording part); therefore, Chow anticipates the invention as claimed.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al. (US Pat. 4,756,884 and 4,963,498) in view of either Galen et al. (US Pat. 5,695,949) or Phillips et al. (US Pat. 5,179,005 and 5,426,032).

See previous office action for the disclosure of Hillman et al. in view of either Galen et al. or Phillips et al.

In response to applicant's argument that the recording part of the instant invention is not suggested by Galen et al. or Phillips et al., applicant is reminded that claim 20 recites "a

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recording part which is detachable from said assay part for the storage of assay information generated by said assay part". Galen et al. specifically disclose in column 13, lines 44-50, that the output of the detector is processed by "a microprocessor for data processing." Phillips et al. disclose in column 9, lines 22-36, a microprocessor to control, read, and store data from the assay strip. Therefore, either Galen et al. or Phillips et al. suggest the recording part of the instant invention.

In response to applicant's argument that the examiner's motivation to combine the references is not the same as applicant's, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that Galen et al. and Phillips et al. do not disclose a detachable recording part to record the data produced by the assay, applicant is directed to Figure 4 of Galen et al. and Figures 3 and 4 of Phillips et al. which clearly show a separate recording part that is detachable from the assay part.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham, Ph.D., whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Minh-Quan K. Pham, Ph.D.  
October 2, 2000



**LONG V. LE**  
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